

Application No. 09/521,086
Amdt. Dated 10/06/2004
Reply to Office Action of 04/09/2004

REMARKS

Status of Claims

Claims 20-31 are pending in the instant application. Claims 20-23 have been canceled and replaced with claims 32-39. Claims 24-31 have been withdrawn from consideration. Claims 32-39 remain for consideration upon entry of the present Amendment. Support for the newly added claims is found in the claims and specification as originally filed. No new matter has been added.

REJECTION UNDER 35 USC § 103

Claim 20 has been rejected under 35 USC § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,110,204 to Lazarov (hereinafter "Lazarov") in view of U.S. Patent No. 4,973,493 to Guire (hereinafter "Guire"). This rejection is transversed and reconsideration is requested, particularly in view of cancellation of Claim 20 and of the clarifying addition of new claim 32.

Lazarov is directed to an implant comprising a substrate that has been coated with a chemical compound of the formula MN_xO_y where M is a metal selected from Group IVA of the periodic table, N is nitrogen and O is oxygen. Lazarov is distinguished from prior art implants in that the surface coating has properties which inhibit the activation of fibrinogen.

Guire is directed to a method of providing a device with an effective biocompatible surface comprising employing a biocompatible agent and a chemical linking agent having a photochemically reactive group capable, capable upon activation, of covalently bonding to separate molecules of the biocompatible agent. A

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biocompatible effective surface is thus formed of separate molecules of a biocompatible agent covalently linked, through a linking moiety, to the solid surface of the device. Albumin is disclosed as a biocompatible agent, which, when used in the method claimed, would inhibit coagulation at the site where the device is located.

The Examiner states "it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply albumin to the surface of the implant taught by Lazarov. The motivation for doing so would have been to improve the thromboresistance of the implant". The Examiner further states that the "implant taught by Lazarov in view of Guire is understood to read on the claimed implant made by contacting the implant for a limited time with a solution of albumin".

Applicant submits that neither the Lazarov or Guire reference teach or suggest the instant invention as currently recited in claim 32, either separately or taken together. Furthermore, there is no teaching or suggestion that the Lazarov and Guire references be combined to form the instantly claimed doubly-coated implant, wherein a first layer of titanium nitrid oxide is directly coated on the implant and a second layer of coating of albumin is applied to the titanium nitrid oxide-coated surface. The Lazarov and Guire references fail as separate references and when combined as suggested by the Examiner to meet the physiochemical properties of the implant as recited in claim 32 of the invention.

The test under section 103 is not whether an improvement or use set forth in a patent would have been obvious or nonobvious; rather the test is whether the claimed invention, considered as a whole, would have been obvious. *Jones v. Hardy*, 110 USPQ 1021, 1024 (Fed. Cir. 1984). Moreover, the invention as a whole is not restricted to the specific subject matter claimed but embraces its properties and the problem it solves. *In*

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re Wright, 848 F 2nd 1216, 6 USPQ 1959 (Fed. Cir. 1988). The problem solved by applicant's invention as claimed is to prevent or reduce intimal hyperplasia at the site of implantation, insertion or attachment in or on a mammalian body. This is an entirely different process than fibrinogen activation or coagulation inhibition, which is the problem set forth in the cited references.

Applicant further submits that while the disclosures in Lazarov and Guire may make it "obvious to try" the instantly claimed article, this standard is an inappropriate method of applying the statutory standard of Section 103. The disclosures of Lazarov or Guire give little or no indication of the effect of the instantly claimed implant on intimal hyperplasia. The mere fact that the cited references make it obvious to try to design an improved biocompatible article comprising titanium nitrid oxide and albumin, however, does not by itself render the improved article obvious. Unless there is some suggestion in the cited references that the approach taken by the Applicant to generate an improved implantable article will work to prevent or reduce intimal hyperplasia at the site of implantation, the approach is not obvious. Thus, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, reconsideration and removal of the rejection is respectfully requested.

Claims 20-23 have been rejected under 35 USC § 103(a) as allegedly being unpatentable over U.S. Patent No. 3,755,823 to Hancock (hereinafter "Hancock") in view of U.S. Patent No. 6,110,204 to Lazarov (hereinafter "Lazarov") and U.S. Patent No. 4,973,493 to Guire (hereinafter "Guire"). This rejection is transversed and reconsideration is requested, particularly in view of cancellation of Claims 20-23 and of the clarifying addition of new claims 32-39.

The Examiner alleges the "the implant taught by Hancock in view of Lazarov and

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Guire is understood to read on the claimed implant made by contacting the implant for a limited time with a solution of albumin. The examiner takes this position because the implant taught by Hancock in view of Lazarov and Guire comprises the same layers comprising the compositions as the claimed implant”.

Applicant has noted in detail the deficiencies in Lazarov and Guire as references of obviousness art. The addition of Hancock, which is merely directed to a coronary stent comprised of stainless steel, does not cure these deficiencies. Thus, the rejection of claim 20 (which is now new claim 32) cannot be properly maintained. Furthermore, the rejection of claims 21-23 (now new claims 33-39) which depend on claim 20, cannot be maintained in view of Applicant’s argument, stated above. Thus, Applicants’ submit that the Examiner has not established a *prima facie* case of obviousness. Inasmuch as the Hancock reference in view of Lazarov and Guire does not teach or suggest the improved article recited in independent claim 20 (new claim 32), the Examiner’s rejection under §103(a) is also improper. Accordingly, reconsideration and removal of the rejection for claims 20-23 (new claims 32-39) is respectfully requested.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the claims as re-drafted are allowable. All issues raised by the Examiner have been addressed.

Applicants hereby petition for a three-month extension of time in order to file a Response to the Office Action on the above-identified application. A check in the amount of \$980.00 is enclosed for the extension. Applicant believes no further fees are due. However, authorization is hereby given to charge our Deposit Account No. 13-0235 in the event any such fees are owed.

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